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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,529	10/25/2003	Farzin Sarem	046190/270365	9904

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EXAMINER	
DOE, SHANTA G	

ART UNIT	PAPER NUMBER
1743	

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09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,529	SAREM ET AL.	
	Examiner	Art Unit	
	Shanta G. Doe	1709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9-13,15-18,and 21 -30* is/are rejected.

7)☒ Claim(s) *2-8,14,19 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/25/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/25/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application FR 01.05651 filed in France on April 26, 2001. It is noted, however, that applicant has not filed a certified copy of the FR 01.05651 or the PCT/FR02/01472 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the main container". There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 9-11 and 21-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, of U.S. Patent No. 6,271,027 in view of Hallsby (US 5187084).

Regarding claim 1, US patent 6,271,027 discloses a device for culturing cells and tissue, the device being of the type comprising at least one culture well arranged to define a chamber suitable for receiving cells or tissue to be cultured, first and second reservoirs (tanks) each housing at least one flexible bag (pocket), at least one of the bags of the reservoirs being suitable for receiving a culture fluid, link means coupled to said well and to said bags to enable the culture fluid to flow from one reservoir to the other via said well, pressurization means arranged to apply to the bags of the first and second reservoirs respective first and/or second sequences of external pressures defined by at least one control module for causing the culture fluid to flow through said well. However, US 6,271,027 fails to disclose the cell culture device above being characterized in that it includes temperature regulation means controlled by said control module and arranged to maintain a first selected temperature or a first selected temperature cycle inside said well and/or to subject the culture fluid leaving at

least one of said first and second reservoirs in order to feed said well to a second selected temperature or to a second selected temperature cycle. Hallsby (US 5,187,084) discloses a temperature cycler device having at least one well (110) arranged to form a chamber and a temperature regulation means (chamber 20 having means for developing and maintaining a selected temperature controlled by a controller (130)) (see Hallsby fig 1, col. 1 lines 28 –32, col. 2 45 –55, col. 2, lines 62 –66 col. 4 lines 53 – col.5 line18). It would have been obvious to one having ordinary skills in the art at the time the invention was made to include a temperature regulation means connected to the controller in the apparatus of US 6,271,027 as taught by Hallsby since it was well known in the art at the time of the invention that a reaction is influenced by the temperature at which the reaction is performed, hence, having the temperature regulation means controlled by a controller would provide for a continuous monitoring of temperature of the wells in order to make sure that the temperature of the wells is at temperature at which the cells are still viable or at the appropriate temperature at which the cell metabolic reaction occurs. Furthermore, the device as described by the combination (US 6,271,072 and Hallsby) is capable of being arranged to maintain a first selected temperature or a first selected temperature cycle inside said well and/or to subject the culture fluid leaving at least one of said first and second reservoirs in order to feed said well to a second selected temperature or to a second selected temperature cycle

Regarding claims 9 and 10, US 6,271,072 in view of Hallsby discloses the device of claim 1. However, the combination fails to disclose the device of claim 1 characterized in that the temperature regulation means comprise first and second electric heater elements. Hallsby (US 5,187,084) further discloses a heat regulation means comprising electric heater elements (84, electrical heating elements) (see Hallsby col.2 lines 62 – 66). It would have been obvious to one having ordinary skills in the art at the time of the invention use made to use electric heater element in the device US 6271072 because it was known in the art at the time of the invention to use electric heating elements heat fluids.

Regarding claim 11, US 6,271,072 in view of Hallsby discloses the device of claim 1. The combination fails to disclose that the electric heater comprises heater resistance secured to the walls defining the reservoirs and or the well. It would have been obvious to one having ordinary skill in the art at the time of the invention to have the electric heater of the combined reference be secured to the wall defining the well or reservoir since it was known to use electric heater element comprising resistance secured to the walls (see Hallsby fig. 1 84 and 36) of the enclosure or chamber to be heated.

Regarding claim 21, US 6,271,072 in view of Hallsby discloses the device of claim 1. The combination fails to disclose that the temperature regulation means is

arranged to impart a temperature shock to the inside of the chamber and /or wells. However, it would have been obvious to one having skill in the art at the time of the invention to have the temperature regulation means be arranged to impart temperature shock to the inside of the chamber in order to investigate the temperature shock response in the cell growth of the cultured cells.

Regarding claim 22, US 6,271,072 in view of Hallsby discloses the device of claim 1. However the combination fails to disclose the device of claim 1 characterized in that the temperature regulation means include at least one temperature sensor. Hallsby (US 5,187,084) further discloses a heat regulation means elements that include at least one temperature sensor (temperature sensors 120, 134)(see Hallsby col. 5 lines 8 –18). It would have been obvious to one having ordinary skills in the art at the time the invention was made to include a temperature sensor in the device of US 6,271,072 since at col. 5 lines 8 -18 Hallsby states that the sensor feeds information to the controller, which sets and maintains the temperature profile in order to obviate overheating.

Regarding claims 23 and 24, US 6,271,072 in view of Hallsby discloses the device of claim 1.However, the combination fails to disclose the device of claim 1 characterized in that it includes a cover for isolating at least the wells or the wells and reservoirs from the outside. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a cover for isolating at least the

wells or the wells and reservoirs in the device of US 6271072 in order to prevent contaminants from the environment from contaminating the cell culture sample in the wells.

4. Claims 12, 15-18, 25, and claim 27 - 30 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 24, and 25 of U.S. Patent No. 6,271,027 in view of Hallsby (US 5187084) as applied to claim 1 above.

Regarding claims 12 and 18, 15, 16,17 and 25; these claims are unpatentable over claims 12, 17, 18, 24 and 25 of US patent 6271027 respectively in view of Hallsby as applied to claim 1 above.

Regarding claim 26, US 6,271,027 in view of Hallsby discloses the device of claim 25. The combination fails to disclose the device of claim 25 characterized in that it includes a main fluid circuit feeding the wells and reservoirs of each of the devices in parallel. It would have been obvious to one having ordinary skills in the time of the invention to include a main fluid circuit feeding the wells and reservoirs of the device in parallel in order to feed each of devices in parallel simultaneously and eliminate the need of having one fluid circuit for each of the devices in parallel.

Regarding claims 27 and 28, US 6,271,027 in view of Hallsby discloses the device of claim 25. The combination fails to disclose the device of claim 25 characterized in that it includes a central temperature regulation means controlled by main control unit. However, it would have been obvious to one having ordinary skill in

the art at the time of the Invention to have a central temperature regulation means in the device of US 6,271,027 in order to simultaneously regulate the temperature of the devices in parallel and furthermore, to eliminate the cost of having individual temperature regulation means for each of the devices. Additionally it would have been obvious to one having ordinary skills in the art at the time of the invention to have the central temperature regulation means be controlled by the main control unit of the device in order for temperature and other parameter of the devices (such as the pressure) to be controlled from the same point and simultaneously which is more cost effective and efficient.

Regarding claims 29 and 30, US 6,271,027 in view of Hallsby discloses the device of claim 25. The combination fails to disclose the device of claim 25 characterized in that it includes a main cover for isolating at least wells of each device or wells and reservoirs of each device simultaneously from the outside. However, It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a cover for isolating at least the wells or the wells and reservoirs in each of the devices of US 6271072 in order to prevent contaminants from the environment from contaminating the cell culture sample in the wells.

Allowable Subject Matter

6. Claims 2-8, 14, and 19-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 2-8, the a cell culture device characterized in that the temperature regulation means comprise fluid circuits integrated in the walls defining the wells or reservoirs and arranged to enable heat conveying fluid to circulate there through could not be found in the prior art alone or in combination.

Regarding claim 14, the cell culture devices characterized in that a portion of the pressurization circuit includes a sub-portion immersed in heat-conveying fluid contained in a container could not be found in the prior art.

Regarding claims 19, the cell culture device wherein the at least one nutrient container and gas or fluid feed line devices are connected to thermostat circuits could not be found in the prior art.

Regarding claims 20, the cell culture device wherein each of the reservoir portions is connected to a heating fluid circuit could not be found in the prior art

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanta G. Doe whose telephone number is 571-270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm(alternate Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GSD

Walter D. Griffin

WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER